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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,511	02/20/2002	Holger Bengs	29988/AX98148	4099

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EXAMINER	
TRAVERS, RUSSELL S	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,511	BENGS ET AL.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The arguments filed November 5, 2003 have been received and entered into the file. These arguments are moot in view of the newly presented action on the merits.

Claims 1-15 are presented for examination.

Applicant's election with traverse of Group I claims 1-12 and 14-15 13 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Examiner neither understand unity of invention, nor describes the unique technical feature unifying the instant invention. This is not found persuasive because Examiner fully understands unity of invention (see paper 9, page 2, paragraph 2) and recited those guidelines governing unity determinations from the Patent Cooperation Treaty. To possess unity of invention, a group of related inventions must a special technical feature to unify the disparate claimed inventions. In the instant case, various therapeutic and cosmetic compositions are recited; and a product by process is recited. This product is amylose, no special technological feature was attributed to that amylose recited, save the source. Thus, claim 13 fails to embody a special technical feature linking amylose compounds to those several compositions of matter herein claimed. And therefore lacks unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim 13 is withdrawn from consideration as reading on non-elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither what compounds would reside under the either the "biotechnologically obtained", or the "biocatalytically" obtained penumbra, nor what processes would need to be employed to obtain a compound that was "biotechnologically obtained", or "biocatalytically" obtained. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of compounds which are "biotechnologically obtained", or "biocatalytically" obtained examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all compounds residing under the either the "biotechnologically obtained", or the "biocatalytically" obtained penumbra, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-12 and 14-15 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-12 and 1 4-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 and 14-15 are rendered indefinite by the phrases "biotechnologically obtained", or "biocatalytically" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are either "biotechnologically obtained", or "biocatalytically" obtained and useful for practicing the invention as envisioned are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kossmann et al.

Attention is directed to Kossmann et al (page 1, paragraph 2) teaching the instant amylose compounds as useful for producing non-toxic films, seen as indistinguishable from those compositions herein claimed.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-10 and 14-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Kossmann et al.

Kossmann et al teach the herein claimed amylose compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for producing various films (see page 1, paragraph 2). Claims 6, 8-10 and 14-15, and the primary reference, differ as to:

1) recitation of biotechnologically obtained, and

2) intended use.

The instant claims are directed to employing a biochemical process for obtaining an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate compound are not probative. It is well settled patent law that a product by process reads on the product. In the instant case Examiner need not reach this ruling. Attention is directed to Kossmann et al, page 25, paragraph 2, setting forth the synthesis of insoluble amylose by employing various immobilized enzymes. Possessing these teachings the skilled artisan would have seen the production of the claimed amylose as residing in the skilled artisan's possession.

Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

Claims 11 and 12 are rejected under 35 U.S.C. § 103 as being unpatentable over Kossmann et al, as set forth above, in view of Ikeda et al and Schneider et al.

Ikeda et al teach the claimed various in soluble starch compounds as old and well known in combination with various pharmaceutical carriers and excipients in lipstick and cosmetic formulations (see table 11). These excipients and carriers are taught as useful for producing various cosmetic films, as herein claimed. Schneider et al teaches those linear amylose compounds as herein claimed as old and well known powder excipients useful for general formulation, as herein claimed. Claims 14-15 and 14-15, and the primary references, differ as to:

1) recitation of biotechnologically obtained, and

2) intended use.

The instant claims are directed to employing a biochemical process for obtaining an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate compound are not probative. It is well settled patent law that a product by process reads on the product. In the instant case Examiner need not reach this ruling. Attention is directed to Schneider et al (see claims 1-6), setting forth the synthesis of insoluble amylose useful for formulating any useful product requiring starch powder. Possessing these teachings the skilled artisan would have seen the production of the claimed amylose as residing in the skilled artisan's possession.

Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617